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22850	7590	06/17/2004	EXAMINER	
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			JOYNES, ROBERT M	
			ART UNIT	PAPER NUMBER
			1615	

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Please find below and/or attached an Office communication concerning this application or proceeding.



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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 09/913,720  
Filing Date: August 31, 2001  
Appellant(s): PETEREIT ET AL.

*File mailed  
6-17-04*

\_\_\_\_\_  
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**EXAMINER'S ANSWER**

This is in response to the appeal brief filed March 24, 2004.

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**(1) *Real Party in Interest***

A statement identifying the real party in interest is contained in the brief.

**(2) *Related Appeals and Interferences***

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

**(3) *Status of Claims***

The statement of the status of the claims contained in the brief is correct.

**(4) *Status of Amendments After Final***

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

**(5) *Summary of Invention***

The summary of invention contained in the brief is correct.

**(6) *Issues***

The appellant's statement of the issues in the brief is correct.

**(7) *Grouping of Claims***

Appellant's brief includes a statement that claims 1-8, 10 and 11 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

**(8) *Claims Appealed***

The copy of the appealed claims contained in the Appendix to the brief is correct.

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**(9) Prior Art of Record****5,705,189                      Lehmann et al.                      01-1998****5,548,033                      Vetter et al.                      08-1996****(10) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-8 and 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lehmann et al. (US 5705189) in combination with Vetter et al. (US 5548033).

Lehmann is relied upon for teaching thermoplastic materials that are copolymers of acrylic and/or methacrylic acid, methacrylate and alkyl ester of acrylic and/or methacrylic acid. See Col. 2, lines 52-65. These copolymers are molded into capsules or capsule halves. See Col. 2, lines 62-65. These capsules are formed by injection molding a melt of the copolymers at temperatures of 120° to 180° C. See Col. 2, line 66 – Col. 3, line 2; Col. 4, lines 3-6; Example 1. Additional materials can be added to the thermoplastic material copolymer such as plasticizers, fillers, dyes, pigments, preservatives, flavoring substances, active substance, and mold-release agents. See Col. 3, line 62 – Col. 4, line 13. The polymers can be formed by extrusion. See Col. 3, lines 10-20. Lehmann does not expressly teach that the copolymer melt is devolatilized by extrusion.

Vetter is relied upon for teaching a method of processing plastic melts wherein the plastic is a poly(methyl methacrylate) and the melt is subject to extrusion to devolatilize the melt. See Col. 5, line 13 – Col. 6, line 6.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include the step of devolatilization by extrusion to a process of preparing capsule from thermoplastic melts of copolymers of acrylic and/or methacrylic acid, methacrylate and alkyl ester of acrylic and/or methacrylic acid. Lehmann teaches a method of making capsule through injection molding with the same material as are claimed in the instant application. Lehmann teaches that the capsules are bubble free and fissure free and can be formed by extrusion. Vetter teaches a method of forming plastics in which the extrusion step of the process devolatilizes the polymer from impurities or unwanted monomeric units as well as water. It is the position of the Examiner that it would have been obvious to use the extrusion step to devolatilize the polymeric composition to remove the risk of the mixture being subject to non-homogeneous changes that could cause bubbles and fissures.

**(11) Response to Argument**

Appellants first argue that the Examiner has admitted that the Lehmann reference does not teach that the polymer composition is devolatilized and the Vetter reference does not teach the devolatilization of untreated poly(methyl methacrylate) polymer as recited in the instant claims. See the Appeal Brief at page 3-4. Appellants are correct in stating the Lehmann reference does not expressly teach that the extrusion step is the devolatilization step of the process. But Lehmann does teach that an extrusion step can be performed while forming the capsules with the same polymers. The Vetter reference is being used to show that the extrusion step is known in similar methods with the same or similar polymers as a devolatilization step in the process. The

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instant claims do not recite that the polymer must be untreated, as is argued, nor do the claims recite what is being devolatilized by the step of the method. It is the position of the Examiner that the Lehmann reference teaches the inclusion of an extrusion step in the method of forming the capsules with the same polymers and that the Vetter reference shows such a step to be used to devolatilize the polymeric composition.

Second, appellants argue that the Vetter reference includes the addition of water to the composition while the instant invention does not include this step in the process. See the Appeal Brief at page 4-5. First, the instant claims do not exclude the positive inclusion of water to the process. The use of comprising language in the instant claims allows for other components, active or inactive, to be present in the composition. The Vetter reference is being used, again, to teach that the extrusion step of these types of methods is used to devolatilize the polymeric composition. Vetter is not being used to show the positive addition of water to the composition. Therefore, it is the position of the Examiner that while Vetter does teach the inclusion of water the instant claims do not exclude the addition of water and the use of comprising language allows for the addition of other components.

Third, appellants argue that the Vetter reference does not include a mold-releasing agent in its composition and the Vetter is not combinable with the Lehmann reference. See the Appeal Brief at page 5. Vetter is not being relied upon for its teaching or not teaching of mold-releasing agent but rather for its teaching that the extrusion step is known to be used in injection molding processes to devolatilize the polymeric compositions. The Lehmann reference does include a mold-releasing agent

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its composition. Further, it is the position of the Examiner that the references are combinable because they both teach injection molding techniques with the same or similar polymeric materials. Lehmann does include pharmaceuticals in its composition with an extrusion step and Vetter, while not including a pharmaceutical agent, teaches that the extrusion step is known to devolatize the polymeric composition in injection molding methods. Therefore, the references are combinable.

Fourth, appellants argue that the method of the instant claims achieves superior results over comparable examples that are very close to examples of the Lehmann reference. See the Appeal Brief at page 5-6. Appellants point out that after running the instant claimed method for 300 times no residue was left on the surface of the mold while the comparable example showed residue, specifically glycerol monostearate, on the mold after 14 runs. See the Appeal Brief at page 5-6. Stull further, appellants indicate that comparative Example 3 includes a mold release agent within the recited range of the instant claims but lacks a devolatization step that produces surface defects in the capsules. See the Appeal Brief at page 5-6. A couple of points can be noted about the results discussed by the appellants. First, Example 1 and comparative example 2 do not use the same mold release agent nor are the mold release agents used in the same amounts. Second, these two examples are produced at different temperatures. The Examples 1 polymeric melt is extruded at a temperature of 180 degrees Celsius while the comparative example is extruded at 160 degrees Celsius. It is difficult for the Examiner to assess these results properly when such differences occur in the formation of the examples to be compared. The instant claims are not

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drawn to a specific release agent yet appellants are arguing that one agent shows better results than another and at different concentrations. The difference in melt temperatures is also curious in that this *may* lead to the difference in the composition releasing from the mold but the Examiner is unable to determine which of these factors or differences lends itself to achieving superior results. Therefore, it is the position of the Examiner that while superior results may have been achieved it is unclear which factors in the experiments lead to the superior results (i.e., the specific release agent, the extrusion temperature, the release agent amount) and which if any of these factors are recited as limitations in the instant claims to distinguish the claims over the prior art of record.

Finally, appellants argue that Claim 3 should stand or fall separately from the remainder of the claims because Vetter teaches nonionic polymers as opposed to the anionic polymers of the instant claim and no motivation exists to substitute the polymers of Claim 3 with those of Vetter. See the Appeal Brief at page 6. Again, Vetter is relied upon to teach that the extrusion step is used to devolatilize the polymeric composition. Vetter is not relied upon for teaching different polymers to be substituted for those in the Lehmann reference. The Lehmann reference teaches the same polymers as the instant claims. It is the position of the Examiner that the limitations of Claim 3 do not distinguish the claim from the combination of the reference. Further, the combination of the references is proper and teaches the polymers of the instant claims.

For the above reasons, it is believed that the rejections should be sustained.





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Respectfully submitted,

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June 14, 2004

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